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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,631	02/15/2001	Jose A. Fernandez-Pol	42108.0106	2674
21888	7590	11/17/2004	EXAMINER	
THOMPSON COBURN, LLP ONE US BANK PLAZA SUITE 3500 ST LOUIS, MO 63101			COPPINS, JANET L	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,631

Applicant(s)

FERNANDEZ-POL, JOSE A

Examiner

Janet L. Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-53 and 65-114 is/are pending in the application.
- 4a) Of the above claim(s) 13-20, 25-35, 40-53 and 65-114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-24 and 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 13-53 and 65-114 pending in the instant application.

Election/Restrictions

1. Applicant's election of Group VII, claims 21-24 & 38-39, (in part), and 36-37, drawn to methods of using pharmaceutical compositions containing a metal ion chelating agent, wherein the composition is an ophthalmic preparation, in the Response to the Restriction Requirement filed August 23, 2004, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 13-20, 25-35, 40-53, and 65-114, (as well as 21-24 and 36-39 in part, drawn to methods of use other than ophthalmic preparations) withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and function and would require separate search considerations. In addition, a reference that anticipates one group would not render obvious the other and the fields of search are not coextensive.

Claim Rejections - 35 USC § 112

3. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The scope of elected claims 21-24 and 37-39 is confusing and to the best of the ability, the Examiner can ascertain two ways of interpreting the claims:

1) The claims are drawn to metal ion chelating agents that are metal containing complexes,

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or

2) The claims are drawn to chelating agents that are non-metal containing, yet capable of binding to metal ions.

5. Therefore claims 21-24 and 37-39 rejected under 35 U.S.C. 112, second paragraph, for being vague and indefinite, since it is unclear whether Applicants are intending to claim 1) or 2) above. Clarification is requested. The claims also fail to specifically define what is meant by "agent," and therefore do not adequately meet the requirements of 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 21, 24, 36, 39 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 3,474,168, Schayer et al. The '168 patent teaches picolinic acid derivatives in compositions for topical administration, including ophthalmic preparations, please refer to column 3, sixth paragraph from the top. Ophthalmic eye drops are disclosed in column 5, Example 6.

8. The Examiner would like to point out that in claim 36, the recitation "for the control of angiogenesis" is an intended use clause, and in order to patentably distinguish the claimed invention from the prior art, a recitation of the intended use of the claimed invention must result in a **structural** difference between the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to

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a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

9. The Examiner had previously rejected claims 13-53 and 65-111 under 35 U.S.C. 102(f). In view of the fact that Novactyl, Inc., the instant Assignee, is acting on behalf of and as agent for the inventors, the Examiner maintains the rejections to the claims, since the subject matter of the instant application has been previously disclosed in U.S. Pat. No. 5,767,135; 6,127,393; 6,403,618; 6,407,125; 6,410,570; and 6,441,009; which are invented by Jose A. Fernandez-Pol.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 21-24 and 36-39 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 13-15 and 22 of U.S. Patent No. 6,407,125, or claims 1, and 4-7 of U.S. Pat. No. 6,127,393, or claims 1-25 of U.S. Pat. No. 6,410,570, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patents.

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The subject matter claimed in the instant application is fully disclosed in the patents and is covered by the above patents since the patents and the application are claiming common subject matter, as follows: Fernandez-Pol discloses and claims in patents '125, '393, and '570 the same methods of treating diseases including sun burn, inflammation associated with acne, certain cancers, viruses and upper respiratory infections, comprising administering the metal ion chelating agents as instantly claimed, for treating diseases that are mediated by a protein having a metal ion-protein complex.

12. Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the applications that matured into the above patents. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Objections

13. Claims 22-24, 37, and 38 are also objected to as depending from rejected base claims.

Conclusion

14. In conclusion, claims 13-53 and 65-114 are pending, and claims 13-20, 25-35, 40-53 and 65-114 have been withdrawn from consideration. Claims 21-24 and 36-39 stand rejected.

Telephone Inquiry


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
November 10, 2004


CEILA CHANG
PRIMARY EXAMINER
GROUP 1200 / 600